

REMARKS

The Examiner's Office Action mailed April 7, 2008, which rejected all pending claims, has been reviewed. Reconsideration in view of the foregoing amendments and remarks is respectfully requested. Moreover, Applicants have reviewed the Office Action of April 7, 2008, and submit that the following Remarks are responsive to all points raised therein. Applicants believe that currently pending claims 21 and 24 are now in form for allowance.

Status of Claims

Claims 21 and 24 are pending in the application. Support for the amendment to claims 21 and 24 can be found, for example, at page 1, lines 3-10 of the specification. No new matter has been added.

Rejection of Claims 21 and 24 under 35 USC § 112, first paragraph

Reconsideration is requested of the rejection of claims 21 and 24 under 35 USC § 112, first paragraph.

The concentration ranges amendments to claims 21 and 24 in the Office Action Response dated January 31, 2008 were supported by the specification. In particular, cancelled claim 22 was included into claim 21. Additional support for the amendment to claim 21 and new claim 24 can be found, for example, at page 10, line 34 to page 11, line 8 of the specification and at Example 1, Table 1, Group 3 of the specification. One skilled in the art looking at the claims and reviewing the specification and Example 1 would be able to make and/or use the invention. The ranges of each compound are disclosed in the specification and the combination of the two compounds is demonstrated in Example 1 as well as in the specification.

Therefore, applicants respectfully submit that claims 21 and 24 are described in such a way as to enable someone skilled in the art to make and/or use the invention without undue experimentation.

Rejection of Claims 21 and 24 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claims 21 and 24 under §103(a) as being unpatentable over Dorn et al. (US Patent No. 6,232,328).

The claimed invention is directed to a composition for control of acarids selected from the group consisting of ticks and mites. Independent claim 21 recites a composition for control of acarids on mammals that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid. Independent claim 24 recites a composition for control of acarids on mammals comprising a combination of synergistic effective amounts of at least 40% by weight permethrin and from 8 to 10 % by weight imidacloprid.

The subject matter of a claim is prima facie obvious in view of particular references if the Patent Office can demonstrate that (1) the references, alone or together, teach every element of the claims, (2) there is some suggestion or motivation in the knowledge generally available to one of ordinary skill in the art to combine the references, and (3) there is some reasonable expectation of success.

Applicants respectfully submit that Dorn et al. fail to teach or suggest each and every element of independent claims 21 and 24. In particular, Dorn et al. fail to teach or suggest 1) a composition for control of acarids selected from the group consisting of ticks and mites and 2) a composition that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid. Alternatively, for claim 24, Dorn et al. fail to teach or suggest 1) a composition for control of acarids selected from the group consisting of ticks and mites and 2) a composition that includes a combination of synergistic effective amounts of at least 40% by weight permethrin and from 8 to 10% by weight imidacloprid.

Dorn et al. fail to teach or suggest a composition for control of acarids. In particular, Dorn et al. do not teach a composition for control of ticks and mites. Ticks and mites are of the class Arachnida. Dorn et al. teach a method for non-systemically controlling parasitic insects, in particular fleas, lice, and flies. Dorn

et al. only describe insects of the class Insecta such as Anoplura (sucking lice), Mallophaga (biting lice), Diptera (flies), and Siphonaptera (fleas) (See column 6, lines 31-49). In fact, Dorn et al. do not teach or suggest any arthropods of the class Arachnida at all. More specifically Dorn et al. do not teach or suggest ticks and mites at all. As described by Dr. Robert Arther in the declaration filed on January 31, 2008 the class of Insects and Arachnids are distinct. Dorn et al. teach control of insects, such as fleas, lice, and flies, which are members of the Class Insecta, Subphylum Uniramia; whereas the present invention teaches control of acarids, such as ticks and mites, which are members of the Class Arachnida, Subphylum Chelicerata. There are distinct anatomical and physiological differences between these classes and as Dr. Arther notes, compounds that demonstrate activity against insects do not necessarily possess activity against acarids. Therefore, based on the disclosure of Dorn et al., it would not have been obvious to one skilled in the art to use the composition of the present invention to control acarids, specifically ticks and mites.

Dorn et al. also fail to teach a composition that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid, or alternatively, at least 40% by weight permethrin and from 8 to 10% by weight imidacloprid. The Examiner states that the ratio and combination of the two elements would have been routine experimentation because it was known that synergism exists between permethrin and imidacloprid. Applicant again respectfully disagrees. First, Dorn et al. fail to teach or suggest that the combination of permethrin and imidacloprid possess a synergistic effect. Dorn et al. mention that the “active compounds can be present in the form of a mixture with synergists or other active compounds” (line 5-7, column 17, emphasis added). Dorn et al. specify that the **active compounds** include insecticides such as pyrethroids (line 7-9, column 17). Dorn et al. do not teach or suggest that the combination of pyrethroids and agonists or antagonists of the nicotineric acetylcholine receptors are synergistic at all.

Recently, the Supreme Court provided some helpful examples of what combination of elements would be considered obvious or non-obvious. *KSR Int'l*

Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007). In particular, the Court discussed a case wherein the combination of two pre-existing elements, a radiant-heat burner and a paving machine, did not create new synergy because the combination of the two did no more than they would in separate sequential operation.

Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57 (1969). As such, when the combination of two elements, like in this application, provides a synergistic effect, Applicants submit that the combination is non-obvious. For example, as shown in Example 1 of the specification, the combination of permethrin and imidacloprid produced a faster kill of ticks than either permethrin or imidacloprid alone. For example, on Day 28 of the study, permethrin demonstrated only a 79% kill rate, and imidacloprid exhibited only a 39% kill rate, whereas the combination of permethrin and imidacloprid produced a 92% kill rate. As such, the combination of permethrin and imidacloprid provided a synergistic effect over permethrin and imidacloprid alone.

In addition, Applicant contends that the synergistic combination of permethrin and imidacloprid was unexpected at the time of the invention. As discussed in the Declaration by Dr. Arther submitted on January 31, 2008, at the time of the invention, it was known that chloronicotinyl compounds were effective against insects (of the class Insecta), however, these chloronicotinyl compounds did not display any activity against ticks or mites (of the class Arachnida). Similarly, it was known that pyrethroids showed some activity against both insects and acarids, however, the duration of the activity was short and less than desired. As such, the combination and synergy between permethrin and imidacloprid against acarids was unexpected.

Therefore, Applicants respectfully submit that Dorn et al. do not teach or suggest all of the elements of claims 21 and 24 and that the current invention is novel and non-obvious in view of Dorn et al.

Rejection of Claims 21 and 24 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claims 21 and 24 under §103(a) as being unpatentable over Sirinyan et al. (US Patent No. 6,001,858).

Similarly to Dorn et al., Applicants respectfully submit that Sirinyan et al. fail to teach or suggest each and every element of independent claims 21 and 24. In particular, Sirinyan et al. fail to teach or suggest 1) a composition for control of acarids selected from the group consisting of ticks and mites and 2) a composition that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid. Alternatively, for claim 24, Sirinyan et al. fail to teach or suggest 1) a composition for control of acarids selected from the group consisting of ticks and mites and 2) a composition that includes a combination of synergistic effective amounts of at least 40% by weight permethrin and from 8 to 10% by weight imidacloprid.

Sirinyan et al. fail to teach or suggest a composition for control of acarids. In particular, Sirinyan et al. do not teach a composition for control of ticks and mites. Ticks and mites are of the class Arachnida. Sirinyan et al. teach a composition for the dermal control of parasitic insects, in particular fleas, lice, and flies. Sirinyan et al. only describe insects of the class Insecta such as Anoplura (sucking lice), Mallophaga (biting lice), Diptera (flies), and Siphonaptera (fleas) (See column 7, line 65 to column 8, line 15). In fact, Sirinyan et al. do not teach or suggest any arthropods of the class Arachnida at all. More specifically Sirinyan et al. do not teach or suggest ticks and mites at all. As described by Dr. Arther in the declaration filed on January 31, 2008, the class of Insects and Arachnids are distinct. Sirinyan et al. teach control of insects, such as fleas, lice, and flies, which are members of the Class Insecta, Subphylum Uniramia; whereas the present invention teaches control of acarids, such as ticks and mites, which are members of the Class Arachnida, Subphylum Chelicerata. There are distinct anatomical and physiological differences between these classes and as Dr. Arther notes, compounds that demonstrate activity against insects do not necessarily possess activity against acarids. Therefore, based on the disclosure of Sirinyan et al., it would not have been obvious to one skilled in the art to use the composition of the present invention to control acarids, specifically ticks and mites.

Sirinyan et al. also fail to teach a composition that includes a combination of synergistic effective amounts of from 0.1 to 60% by weight permethrin and from 0.1 to 25% by weight imidacloprid, or alternatively, at least 40% by weight permethrin and from 8 to 10% by weight imidacloprid. The Examiner states that the ratio and combination of the two elements would have been routine experimentation because it was known that synergism exists between permethrin and imidacloprid. Applicant respectfully disagrees. First, Sirinyan et al. fail to teach or suggest that the combination of permethrin and imidacloprid possess a synergistic effect. Sirinyan et al. mention the “it is also possible for further active substances to be present with nicotinyl compounds” (line 27-28, column 8). Sirinyan et al. also mention that the **active compounds** include insecticides such as pyrethroids (line 29-31, column 8). In fact, Sirinyan et al. do not teach or suggest that a combination of pyrethroids and agonists or antagonists of the nicotinergeric acetylcholine receptors are synergistic at all.

In addition, as discussed above, Applicant contends, that unlike suggested by the Examiner, the synergistic combination of permethrin and imidacloprid was unexpected at the time of the invention. As discussed in the Declaration by Dr. Arther filed on January 31, 2008, at the time of the invention, it was known that chloronicotinyl compounds were effective against insects, however, these chloronicotinyl compounds did not display any activity against ticks or mites, i.e. acarids. Similarly, it was known that pyrethroids showed some activity against both insects and acarids, however, the duration of the activity was short and less than desired. As such, the combination and synergy between permethrin and imidacloprid against acarids was unexpected.

Therefore, Applicants respectfully submit that Sirinyan et al. do not teach or suggest all of the elements of claims 21 and 24 and that the current invention is novel and non-obvious in view of Sirinyan et al.

Rejection of Claims 21 and 24 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claims 21 and 24 under §103(a) as being unpatentable over Elbert et al. (Brighton crop protection Conference, 1990, pages 21-28) and Shiokawa et al. (US Patent No. 4,742,060).

Applicants respectfully submit that Elbert et al. alone or in combination with Shiokawa et al. fail to teach or suggest each and every element of independent claims 21 and 24. In particular, Elbert et al. alone or in combination with Shiokawa et al. at least fail to teach or suggest 1) a composition for control of acarids on mammals and 2) a composition for control of acarids selected from the group consisting of ticks and mites. Alternatively, for claim 24, Elbert et al. and Shiokawa et al. fail to teach or suggest 1) a composition for control of acarids on mammals and 2) a composition for control of acarids selected from the group consisting of ticks and mites.

Elbert et al. fail to teach a composition for the control of acarids on mammals. Rather, Elbert et al. teach the use of imidacloprid to treat plants or the soil for insects. Applicant's invention is directed to the control of acarids on mammals.

In addition, Elbert et al. fails to teach a composition for the control of acarids selected from the group consisting of ticks and mites. In particular, Elbert et al. fail to teach a composition for the control of ticks and mites of the class Arachnida. Elbert et al. teaches the effectiveness of imidacloprid for control of insects of the class Insecta, specifically of the orders Coleoptera, Diptera, and Lepidoptera. Elbert et al. also teaches the insecticidal activity of imidacloprid against sucking insects such as leafhoppers, planthoppers, aphids, termites, jassids, and thrips, all falling under the class Insecta. Finally, Elbert et al. teaches control of soil pests such as beetles, wireworms, Collembola, and millipedes. As such, Elbert et al. teach control of insects within the class Insecta. But Elbert et al. fail to teach control of ticks and mites of the class Arachnida. In fact, Elbert et al. do not teach control of ticks and mites at all.

Shiokawa et al. fail to cure the deficiency of Elbert et al. as Shiokawa et al. also do not teach a composition for the control of ticks and mites of the class

Arachnida. Shiokawa et al. teach effectiveness against insects (of the class Insecta) and worms, not ticks and mites (of the class Arachnida).

Therefore, Applicants respectfully submit that Elbert et al. alone or in combination with Shiokawa et al. do not teach or suggest all of the elements of claims 21 and 24 and that the current invention is novel and non-obvious in view of Elbert et al. and Shiokawa et al.

Conclusion

In view of the above, Applicants respectfully submit that the pending claims are novel and not obvious over the cited references and request withdrawal of all rejections and allowance of the claims.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment in connection with this amendment to Deposit Account No. 50-4260.

Respectfully submitted,
/JESSICA MONACHELLO/
Jessica Monachello
Reg. No. 58,015
BAYER HEALTHCARE LLC
P.O. Box 390
Shawnee Mission, KS 66201
Tel: 913-268-2038
Fax: 913-268-2889